

Special considerations for developing country vaccines

*Designing routine and pandemic vaccines to meet
the needs of immunization programs in low and
middle income countries*

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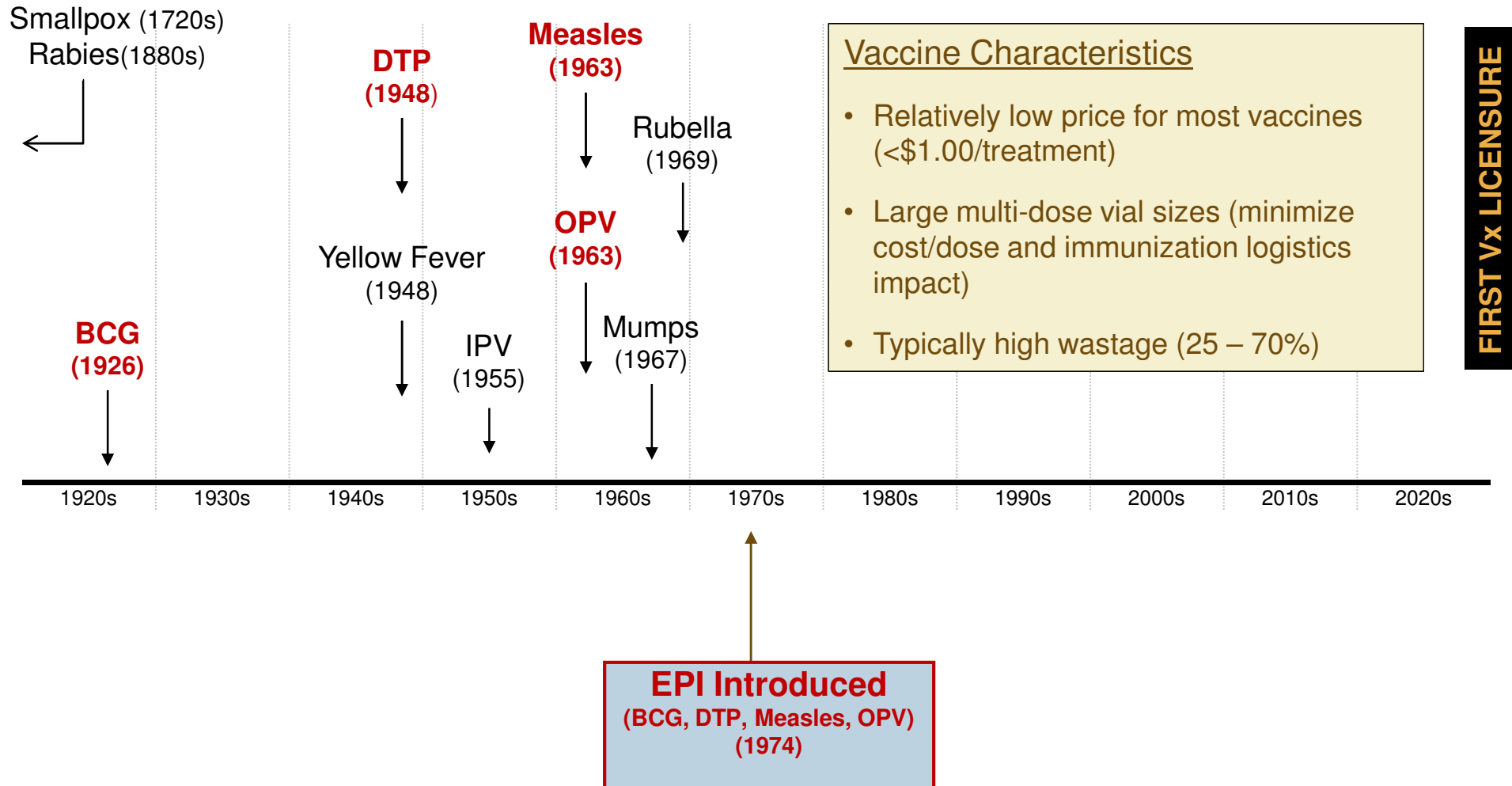
IVTW meeting | September 17 & 18, 2010

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Immunization systems and technologies for tomorrow

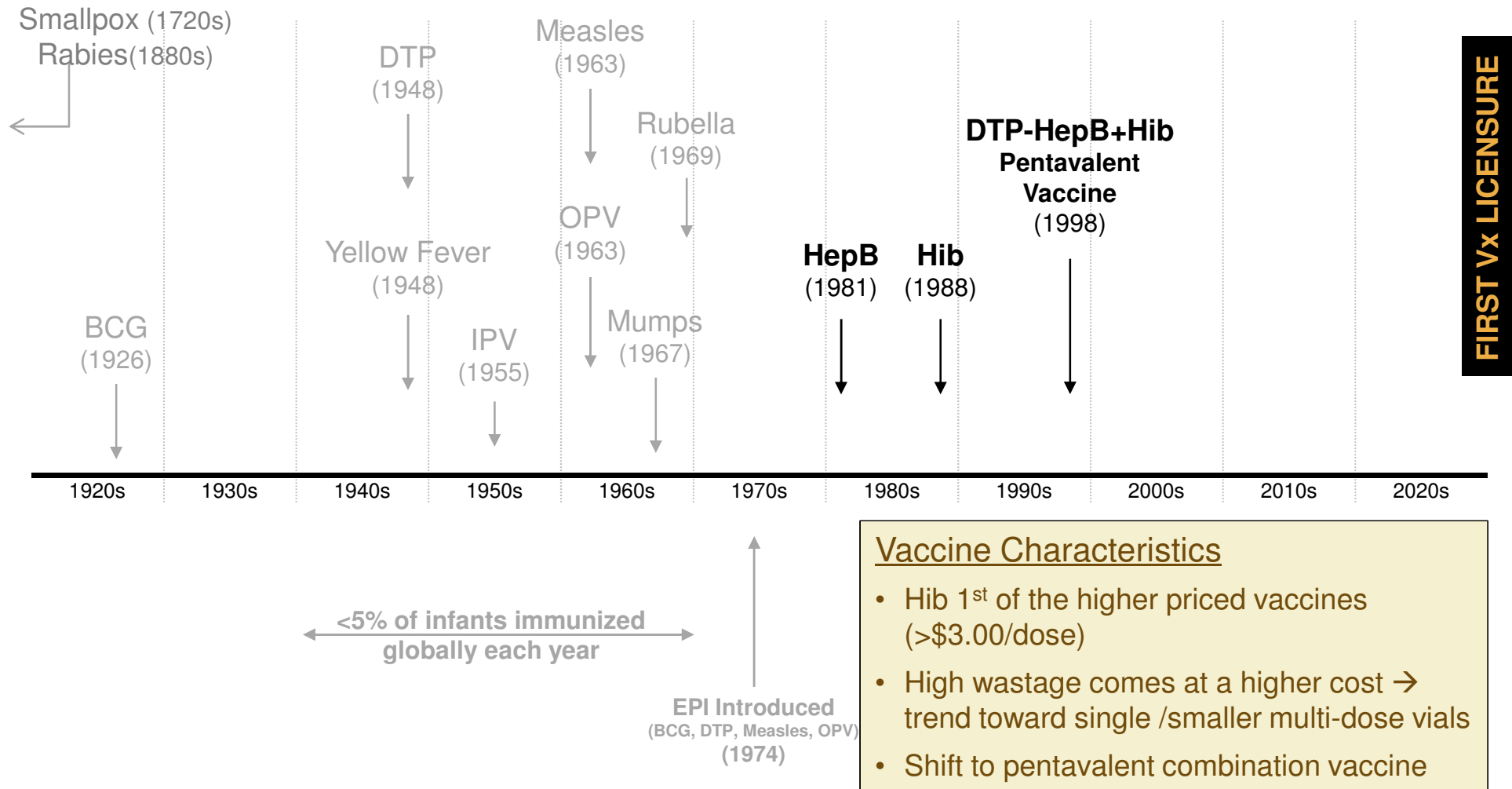


Vaccine Landscape (1920 – 1970)



3 Special considerations for developing country vaccines

Vaccine Landscape (1980s)

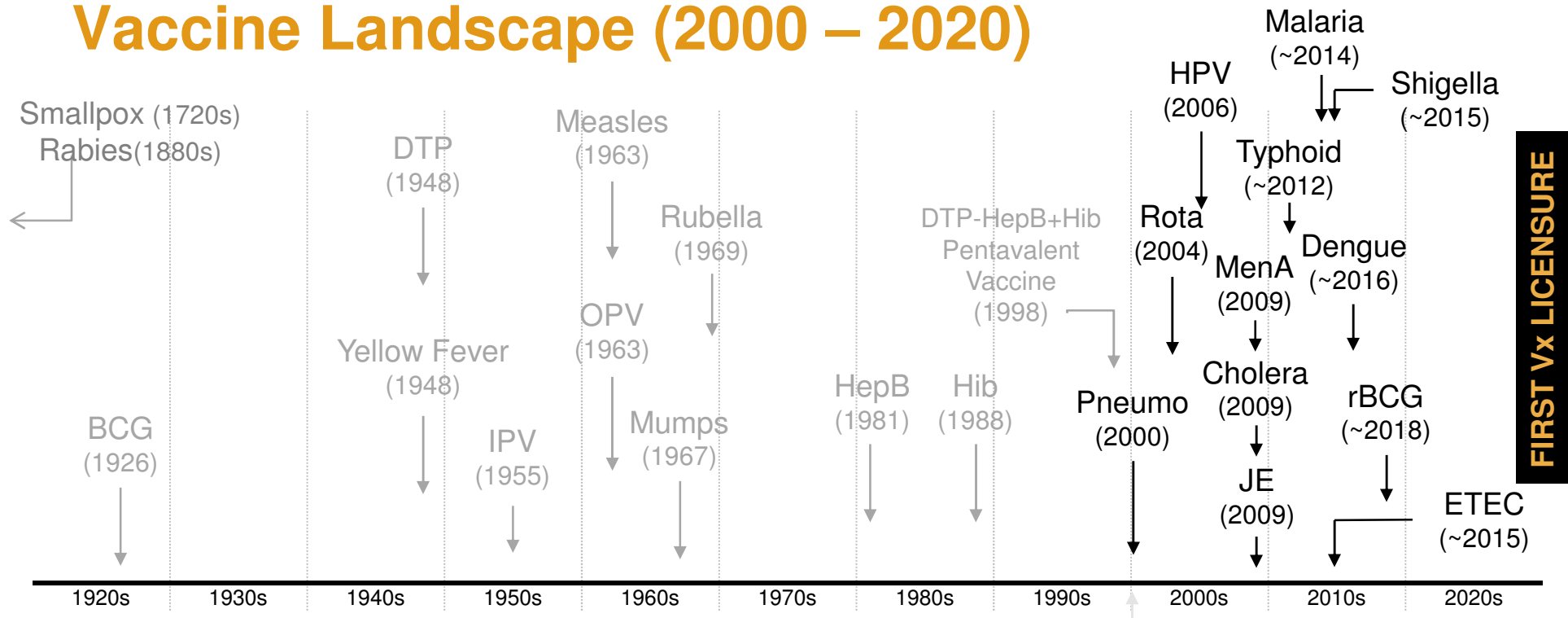


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4 Special considerations for developing country vaccines

Vaccine Landscape (2000 – 2020)



1920 – 1939: 1 vaccine
1940 – 1959: 3 vaccines
1960 – 1979: 4 vaccines
1980 – 1999: 3 vaccines
2000 – 2019: ≥12 vaccines



Impact and challenges of **routine** vaccine introduction

Volumes for storage and transportation



MK144: WHO approved ice-lined refrigerator, net capacity 45L

How many doses would fit in this fridge*?

9000	Polio (<i>20-dose vials</i>)
1098	Hepatitis B (<i>10-dose vials</i>)
348	Liquid Pentavalent (<i>single dose vial</i>)
300	HPV (<i>single dose vial</i>)
80	Pneumo (<i>pre-filled syringe</i>)

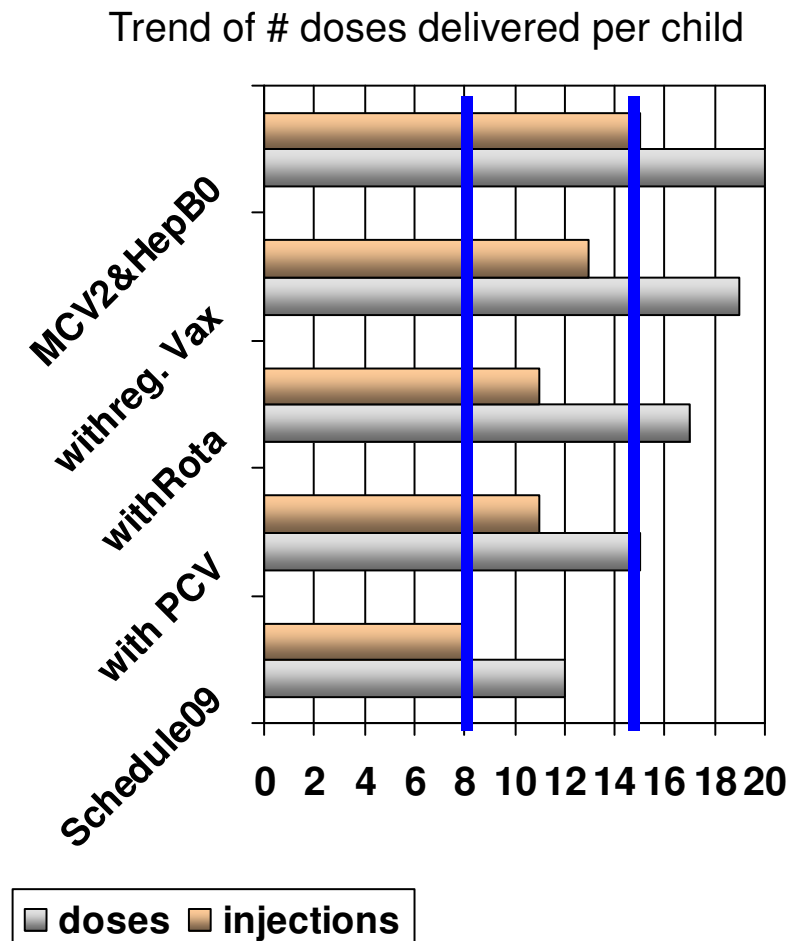
Based on the following image and packaging (source WHO vaccine volume calculator, 2009): **Polio- 0.5cm³ (mOPV1, 20-dose vials, boxes of 10 vials); **Hep B**- 4.1 cm³ (10-dose vials, boxes of 25 vials); **Penta**- 12.9 cm³ (packs of 50 single dose vials); **HPV**- 15cm³ (pack of 10 single-dose vials); **Pneumo**- 55.9 cm³ (packs of 10 single doses+ syringe).*

Injection safety

- Increasing risk of programmatic errors in handling more vaccines, often in complex presentations

Waste management

- Increasing environmental and financial impact from more injection waste



Human resources

- Increased time necessary for:
 - Stock management, inventory, ordering etc.
 - Service delivery and record keeping by health care workers
- New training required
- Supervision must be increased



Packaging & Presentation



**Initial rotavirus vaccine
lyophilized, no VVMs
Full course: 330 cm³**



**Second generation
rotavirus vaccine, no
VVMs, liquid
Full course: 170.6 cm³**



**Latest rotavirus
vaccine, VVMs,
Full course: 34 cm³***

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Cold Chain volume per dose (cm³) varies by secondary packaging: in one dose carton 115.3; in 10 dose carton 43.3; in 50 dose carton 17.1 : *Source: WHO vaccine volume calculator. 2009*

Impact and challenges of **pandemic** vaccine introduction

Accelerated vaccine development timeline

Products are coming to market in presentations that are challenging to introduce

Of the 10 WHO prequalified H1N1 vaccines*

- NONE included a VVM
- *NONE allowed for controlled temperature storage outside of the 2-8°C range*
- 2 of 10 were freeze stable
- *2 of 10 were multi-component vaccines that required preparation prior to use*

Rapid Deployment

- **1-December-2009** *First H1N1 vaccine WHO prequalified**
- **7-January-2010:** *First developing country receives vaccines from WHO***

Key steps required prior to vaccine introduction***:

- **Funding secured**
- **Ministerial order/approval** of the campaign
- **Vaccination strategies developed**
 - *Target groups, vaccination sites, administration route etc.*
- **Deployment plans developed**
 - *Inc. equipment for cold storage, transportation; staffing; waste mgmt.*
- **Monitoring and surveillance** of disease and AEFIs
- **Training sessions** for health care workers

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* = GSK's Arepanrix; ** = Mongolia receives first shipment from WHO; *** = from National Pandemic Vaccine Deployment Plan, Maldives

New target groups

- Vaccines need to be delivered to new and/or non-traditional populations, requiring additional infrastructure and education

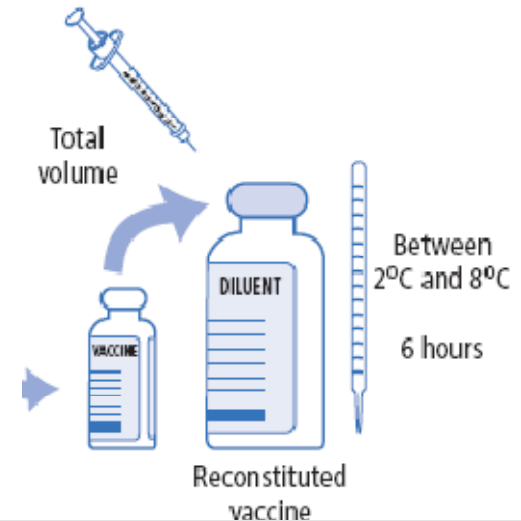
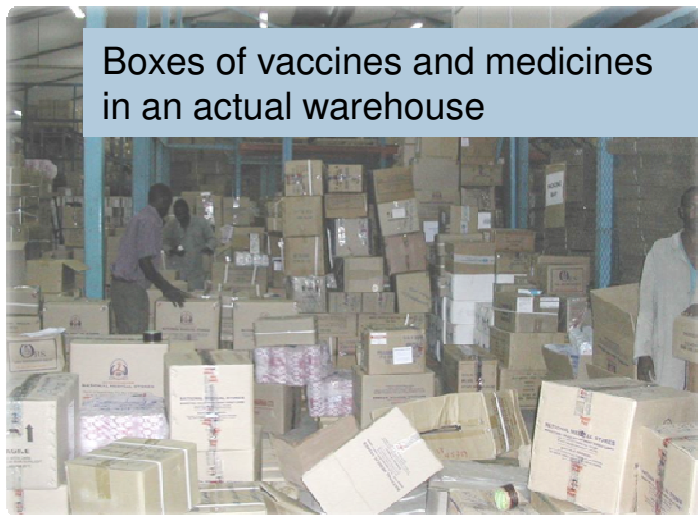
For H1N1, this included*

- *Children from 6 months-18 years of age*
- *Young adults form 19-24 years of age*
- *Household members of children under 6 months of age*
- *Persons aged 25-64 years with health conditions associated with higher risk of medical complications*

Preparing systems for **routine** and **pandemic** vaccine introduction

Need to work on two fronts

- In countries to strengthen and improve systems
- Upstream to design more suitable products



Complex presentation leads to higher potential for errors

Presentation and packaging in line with the Generic Preferred Product Profile (gPPP)

Recommendations on presentation and packaging of new vaccines for use by public-sector programmes in developing countries.

Developed through collaboration with the public sector (WHO, UNICEF, PATH, CDC, JSI) and the private sector (IFPMA, DCVMN)

Recommendations based on evidence in the following areas

- Formulation
- Packaging
- Presentation
- **Work programme**
 - Identifies areas where more evidence is required

WHO's Programmatic Suitability for Pre-Qualification

Identified need to define the characteristics that determine programmatic suitability

Objectives:

- Identify characteristics that define whether a vaccine is suitable for the immunization services where it is intended to be used
- Outline a process for reviewing candidate vaccine characteristics and deciding if they meet the programmatic suitability PQ requirements.



DRAFT Characteristics

MANDATORY	CRITICAL	PREFERRED
<ul style="list-style-type: none"> •Co-administration with other vaccines •Antimicrobial preservative •Dose volume, injectable* •Thermostability / storage* 	<ul style="list-style-type: none"> •Schedule •Auto-disable syringe •Dose volume, injectable* •Antimicrobial preservative •Handling •Visual cue regarding handling and discard •Primary container • Heat exposure indicator, primary container (VVM) •Thermostability / storage* •Materials* 	<ul style="list-style-type: none"> •Maximum packed volume •Dose volume, oral •Doses per primary container •Doses per secondary container •Process of preparation & administration •Thermostability / storage* •Materials*

* these characteristics have values in more than one category.

What the criteria mean

DRAFT Characteristic*	Type	Details
Dose volume, injectable vaccine	Mandatory	Should not exceed 1ml per dose for paediatric indication
Heat exposure indicator, primary container (VVM)	Critical	Agencies purchasing vaccines should request manufacturers to supply all vaccines with VVMs....
Thermostability/storage	Preferred	Storage of vaccines and diluents at temperatures above +8°C, especially for freeze sensitive vaccines

Join the discussion!

Keep up-to date!

- VPPAG online: <http://sites.google.com/site/vppagp/>
- Optimize eNewsletter (optimize.who@path.org)
- TechNet forum (www.technet21.org)
 - Technical Network for Strengthening Immunization consultation meeting:
 - *November 30-December 2, 2010; Kuala Lumpur, Malaysia*
- Michel Zaffran (zaffranm@who.int)

THANK YOU



For more information:

www.technet21.org | www.path.org | www.who.int

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